

Remarks

Claim Status

Prior to the entry of this amendment, claims 1-14 were canceled and claims 15-39 were pending, with claims 15-20, 23 and 30-31 withdrawn from consideration. With the entry of this amendment, claims 1-14 remain canceled, claims 15-39 remain pending, with claims 15-20, 23 and 30-31 remaining withdrawn. Claims 31, 32 and 39 are herein amended.

Double Patenting

The Office provisionally rejected claims 21-22, 24-29 and 32-39 on the ground of nonstatutory obviousness-type double patenting as unpatentable over copending Application Nos. 11/153,728, 11/119,273, and 11/219,273. To facilitate prosecution, Applicant requests that the Office hold all provisional double patenting rejections in abeyance, pending claim allowance.

Rejection of Claim 32, Under 35 U.S.C. § 112, Second Paragraph

The Office rejected Claim 32, under 35 U.S.C. § 112, second paragraph. Applicant herein amends claim 32 to depend from claim 29, rendering the rejection moot, and thanks the Office for proceeding with examination under the assumption that claim 32 depends from claim 29.

Rejection of Claims 21-22, 24-29 and 32-39, Under 35 U.S.C. § 102/103

The Office rejected Claims 21-22, 24-29 and 32-39 as allegedly anticipated or rendered obvious by US 2003/0114389 ("the '389 application"). Applicant traverses for the reasons set forth below.

First, the claimed invention is not anticipated by the '389 application. Claim 21 recites an oral dosage form not obtainable by wet granulation with excipients using water. The '389 application requires the use of water, as disclosed in ¶¶ 78 and 80. Therefore, the '389 application does not disclose all limitations of the pending claims.

Second, the '389 application does not render the claimed invention obvious. A *prima facie* case of obviousness must establish that there is a reasonable expectation of success at arriving at Applicant's claimed subject matter, using the cited art as a starting point. However, the '389 application does not provide a reasonable expectation of success at arriving at a high-dose aliskiren tablet.

Aliskiren is very difficult to formulate and, prior to the claimed invention, it had not been possible to make oral forms in the form of tablets in a reliable and robust way. The flow properties, bulk density, compression behavior and elastic properties pose a formidable

hurdle to achieving the high drug load necessary to achieve a reasonable tablet size. Present application at ¶¶ 6-7. Furthermore, the highly hygroscopic nature of aliskiren makes it inherently unstable, making standard tablet manufacturing processes extremely difficult to achieve. Present application at ¶ 8.

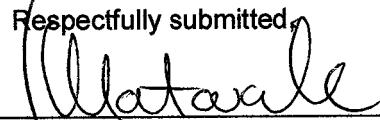
The present application discloses, for the first time, the unexpected finding that an aqueous granulation process leads to a change in polymorphism which negatively affects the stability of the drug product but, in contrast, an organic granulation process produces a superior oral dosage form. The organic granulation process yields a drug substance with improved characteristics such that it can be formulated into stable aliskiren tablets with a high drug load, sufficient hardness and resistance to friability.

The '389 application does not provide a reasonable expectation of success in achieving the claimed invention. It merely states that the disclosed pharmaceutical preparations can be prepared in a manner that is known *per se*. The '389 application at ¶ 67. It provides no disclosure of organic granulation and no data to support a tablet produced in such a manner. At best, the '389 application provides a wish, and is not sufficient to be considered enabling art. It does not provide any expectation that a high-load aliskiren tablet can be produced by organic granulation.

In spite of the unpredictability in working with a drug substance with the unfavorable formulation properties of aliskiren, Applicant invested in, tested and identified a robust high-load tablet. Based on the evidence as a whole, the '389 application does not support a finding of obviousness. It provides no evidence, let alone a reasonable expectation of producing the claimed tablet. Accordingly, Applicant requests that the Office withdraw all grounds for rejection.

Applicant respectfully requests that this Amendment be entered by the Office and asserts that the proposed claims do not raise new issues or necessitate the undertaking of any additional search by the Office, since all the elements and their relationships were either claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Office. If there are any fees due in connection with the filing of this Amendment, please charge the fees to our Deposit Account.

Respectfully submitted,



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